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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 8, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 4

Nicholas Senchyshak
President
Herbarium, Inc.
11016 - 152nd Avenue
Kenosha, Wisconsin 53142

Dear Mr. Senchyshak:

The Food and Drug Administration (FDA) received a complaint regarding injuries sustained by a young woman who experienced an abnormal heart rate with complete heart block, a potentially life-threatening condition. The consumer's symptoms were consistent with an overdose of digitalis-like cardiac glycosides. The young woman experienced this condition after ingesting a regimen of dietary supplements. FDA's investigation determined that the problem was due to the ingredient plantain found in the dietary supplement "Chomper."

FDA's investigation traced this contaminated plantain to your firm. This contamination is associated with plantain that you imported from suppliers in identified as lot numbers 16-121, 16-338, and 15-791, and widely distributed throughout the United States.

The cut plantain leaves and plantain leaves which you processed into powder are adulterated and misbranded under the Federal Food, Drug and Cosmetic Act (the Act) as follows:

1. within the meaning of Section 402(a)(1) in that they contain an added poisonous or deleterious substance, namely lanatosides (cardiac glycosides), which may render them injurious to health.

2. within the meaning of Section 403(a)(1) in that the labeling is false and misleading because it fails to reveal the material fact that the product contains lanatosides, e.g., cardiac glycosides, which, if ingested, can cause life-threatening heart reactions.

FDA collected multiple samples of plantain at various establishments nationwide which had received this material either directly or indirectly from you. The plantain was being sold as such or used or destined for use in the manufacture of dietary supplements, foods, and other products. FDA analyses of these samples showed that the plant material identified as "plantain" contained lanatosides (cardiac glycosides). The presence of lanatosides support that the plant material contains *Digitalis* glycosides. *Digitalis lanata* has been reported to contain these lanatosides. Plantain has not been reported to contain any cardiac glycosides.

FDA also conducted an analysis of a sample of plantain to determine whether the material labeled as plantain actually contained plantain. The analysis found that the characteristic trichomes for plantain were low in concentration in the sample when compared to reference specimens. These analyses indicate that the plantain was contaminated with *Digitalis*.

As an importer, repacker, processor and distributor, you are responsible for ensuring that foods that you import, repack, process or distribute are safe for human consumption. We note that you have voluntarily recalled the adulterated plantain leaves, cut or powdered, that you distributed. However, we are concerned that this type of situation does not occur again.

We request that you notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to preclude this violation from occurring in the future. If you continue to distribute foods that are adulterated and misbranded as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl